4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1588]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exemptions From Substantial Equivalence Requirements for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0684. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Exemptions From Substantial Equivalence Requirements for Tobacco Products

OMB Control Number 0910-0684--Revision

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

The Consolidated Appropriations Act of 2022 (Pub. L. 117-103) (the Appropriations Act), enacted on March 15, 2022, amended the definition of the term "tobacco product" in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) to include products that contain nicotine from any source. As a result, non-tobacco nicotine (NTN) products that were not previously subject to the FD&C Act (e.g., products containing synthetic nicotine) are now subject to all of the tobacco product provisions in the FD&C Act beginning on April 14, 2022, including the requirement of premarket review for new tobacco products.

The FD&C Act, as amended by the Tobacco Control Act, requires that before a new tobacco product may be introduced or delivered for introduction into interstate commerce, the new tobacco product must undergo premarket review by FDA. FDA must issue an order authorizing the commercial distribution of the new tobacco product or find the product exempt from the requirements of substantial equivalence under section 910(a)(2)(A) of the FD&C Act (21 U.S.C. 387j(a)(2)(A)), before the product may be introduced into commercial distribution.

FDA has established a pathway for manufacturers to request exemptions from the substantial equivalence requirements of the FD&C Act in § 1107.1 (21 CFR 1107.1) of the Agency's regulations. As described in § 1107.1(a), FDA may exempt tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, from the requirement of demonstrating substantial equivalence if the Agency determines that: (1) the modification would be a minor modification of a tobacco

product that can be sold under the FD&C Act; (2) a report demonstrating substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health; and (3) an exemption is otherwise appropriate.

Section 1107.1(b) states that a request for exemption under section 905(j)(3) of the FD&C Act (21 U.S.C. 387e(j)(3)) may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that tobacco product and that the manufacturer must submit the request and all information supporting it to FDA. The request must be made in an electronic format that FDA can process, review, and archive (or a written request must be made by the manufacturer explaining in detail why the manufacturer cannot submit the request in an electronic format and requesting an alternative means of submission to the electronic format).

An exemption request must contain: (1) the manufacturer's address and contact information; (2) identification of the tobacco product(s); (3) a detailed explanation of the purpose for the modification; (4) a detailed description of the modification, including a statement as to whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of the existing tobacco additive; (5) a detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the FD&C Act; (6) a detailed explanation of why a report under section 905(j)(1) of the FD&C Act intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; (7) a certification (i.e., a signed statement by a responsible official of the company) summarizing the supporting evidence and providing the rationale for the official's determination that the modification does not increase the tobacco product's appeal to or use by minors, toxicity, addictiveness, or abuse liability; (8) other information justifying an exemption; and (9) an environmental assessment (EA) under part 25 (21 CFR part 25; 42 U.S.C. 4332(2)) prepared in accordance with the requirements of § 25.40 (21 CFR 25.40)).

The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4347) states national environmental objectives and imposes upon each Federal Agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement for every major Federal action that will significantly affect the quality of the human environment.

The FDA NEPA regulations are contained in part 25. All applications for exemption from substantial equivalence require the submission of an EA. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) specifies the content requirements for EAs for non-excluded actions.

The information required by § 1107.1(b) is submitted to FDA so FDA can determine whether an exemption from substantial equivalence to the product is appropriate for the protection of the public health. Section 1107.1(c) states that FDA will review the information submitted and determine whether to grant or deny an exemption based on whether the criteria in section 905(j)(3) of the FD&C Act are met. FDA may request additional information if necessary, to make a determination and may consider the exemption request withdrawn if the information is not provided within the requested timeframe.

This collection of information also contains a requirement that a manufacturer submit a report (referred to as an "abbreviated report") at least 90 days prior to making an introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product. Section 905(j)(1)(A)(ii) of the FD&C Act states that if an exemption has been requested and granted, the manufacturer must submit to FDA a report that demonstrates that the tobacco product is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, and all the modifications are covered by exemptions granted by the Secretary under section 905(j)(3).

Description of Respondents: The respondents to this collection of information are tobacco product manufacturers defined as any person, including any repacker or relabeler, who: (1) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (2) imports a finished tobacco product for sale or distribution in the United States.

Section 1107.1(b) requires that the exemption request and supporting information be submitted in an electronic format that FDA can process, review, and archive. The exemption request and supporting information must be legible and in English. These requirements ensure that FDA can review the exemption request expeditiously and appropriately. FDA provides information on its website on how manufactures may provide electronic submissions and regulatory correspondence, such as the exemption request and supporting information, as well as the abbreviated report, to FDA (e.g., information on electronic media and methods of transmission). Steps on how to prepare and the recommended structure of an exemption request and abbreviated report can be found at: https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/exemption-substantial-equivalence. Information on how to submit exemption requests and abbreviated reports to the CTP Portal can be found here: https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal.

FDA does not anticipate any need to submit an exemption request or supporting information in a non-electronic format. However, a company that is not able to submit the documentation in an electronic format may submit a written request to the Center for Tobacco Products document control center (https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp).

In the *Federal Register* of February 25, 2022 (87 FR 10797), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment responsive to the four information collection topics solicited was received. The comment stated that the Agency should consider making the exemption request pathway (section 905(j)(3) of the FD&C Act) more flexible for new products, devices, and technology innovations.

FDA appreciates the comment and notes that although we may consider the comment, these types of actions may necessitate guidance (as noted in the comment). Currently, we believe that the exemption pathway is providing applicants an efficient pathway to make additive changes to their products and receive a marketing order. If the Agency decides to consider revising the suggested actions, these types of actions would need to be done pursuant to separate notice and comment procedures.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section and/or Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§ 1107.1(b); Optional preparation of tobacco product exemption from substantial equivalence request; and § 25.40; Preparation of an environmental assessment	812	1	812	24	19,488
§ 1107.1(c); Preparation of additional information for tobacco product exemption from substantial equivalence request	150	1	150	3	450
Abbreviated report submitted to demonstrate: tobacco product is modified under section 905(j)(3) of the FD&C Act, modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)	1,217	1	1,217	2	2,434
Total					22,372

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that we will receive 812 exemption requests under § 1107.1(b) for 24 hours per response including EA for a total of 19,488 hours. Since an EA is required for each § 1107.1(b) (Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request), the burden per response for EAs (12 hours) has been combined with the 12 hours for an exemption request for a total of 24 hours per response.

FDA further estimates, that we will receive 150 submissions requiring additional information in support of the initial exemption request, and it is expected that it will take an average of 3 hours to prepare the additional information for a total of 450 hours.

FDA estimates that 1,217 respondents will prepare 1,217 responses and each response will take approximately 2 hours to prepare an abbreviated report, as required by section 905(j)(1)(A)(ii), for a total of 2,434 hours. The estimates reflect a decrease of 1,217 hours to account for a reduction in average response time for preparing an abbreviated report. FDA provides a recommended format for applicants in the exemption order letter that significantly reduces the burden hours for preparing the abbreviated report. Therefore, FDA now estimates that the hours for the collection of information associated with exemptions from substantial equivalence requirements total 22,372 hours.

Although there may be year-to-year variability in the absolute number of exemption requests submitted, FDA considers any trends in our analysis, and the overall number of extension requests from manufacturers of tobacco products has remained consistent. Additionally, although manufacturers of NTN products are now subject to all of the tobacco product provisions in the FD&C Act, including the need to submit premarket submissions to FDA and obtain authorization from the Agency to market their product, FDA expects to receive premarket tobacco product applications for most currently marketed NTN products. FDA does not expect to receive many exemption requests for currently marketed NTN products. Thus, no additional adjustments to the number of respondents in our burden estimate are needed for NTN products as the current estimate accounts for some year-to-year variability in the absolute number of exemption requests submitted.

Dated: August 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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